REMARKS

Claims 1-13 are pending. No amendments have been made by way of the present submission, thus, no new matter has been added.

In view of the following remarks, Applicants respectfully request that the Examiner withdrawal all rejections and allow the currently pending claims.

Issues under 35 U.S.C. §103(a)

The Examiner has rejected claims 1-11 under 35 U.S.C. §103(a) as being obvious over Hong, U.S. Patent No. 5,869,670 (herein "Hong '670") in view of Khomutov et al., *Tetrahedron Lett.*, 42:2887-2889 (2001) (herein "Khomutov"). Applicants respectfully traverse this rejection.

The Examiner asserts that those of skill in the art would be motivated to combine the synthesis process of Gemifloxacin disclosed in Hong '670 with the use of benzaldehyde as a primary amine protecting group as disclosed in Khomutov. The Examiner has further stated that Hong '670 does not require a recrystallization step and that Khomutov teaches a one-pot procedure wherein a Schiff-base type protecting group reacts with a NH_2 group in the presence of a secondary amine. However, Applicants submit that significant patentable distinctions exist between the present claims and Hong '670. Khomutov cannot cure these distinctions.

By way of explanation, the compound actually synthesized by Hong '670 (see Example 180 thereof) is different from the present compound represented by formula 1 (see present claim 1). The present invention provides a process for preparing a specific salt form of the compound synthesized in Example 180 of Hong '670. In particular, the present invention provides a process for preparing this specific salt form without impurities by using a novel intermediate. A review of Examples 7 and 8 of the present invention reveals processes for preparing Gemifloxacine

methanesulfonic acid salt by using the intermediate of Example 1. This intermediate is novel. In contrast, Example 180 of Hong '670 provides a method for preparing Gemafloxacine by using a compound of formula 2, and a trifluoroacetic acid salt of the compound of formula 3 (of the present invention). Therefore, a direct comparison cannot be made between the presently claimed process and the process of Hong '670 due to these differences in intermediates and final products. The secondary reference of Khomutov does not make up for these differences. For this reason alone, there exists no prima facie case of obviousness.

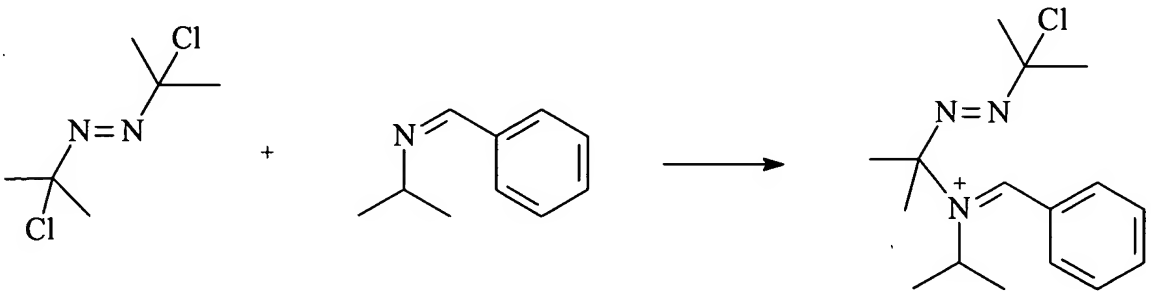
In regard to the above, Applicants request that the Examiner take into consideration the fact that homologous intermediates of the prior art which would not obviously have properties in common with the claimed compounds does not render the latter obvious if there is no motivation to interrupt the prior art synthesis to determine the properties possessed by the intermediates. In re Lalu et al., 747 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984).

Further, the Examiner believes that in the disclosure of Khomutov, a Schiff-base type protecting group selectively reacts with a NH_2 group. Thus, the Examiner asserts that the yield can be increased by reducing by-products such as the compound of formula 8 of the present invention.

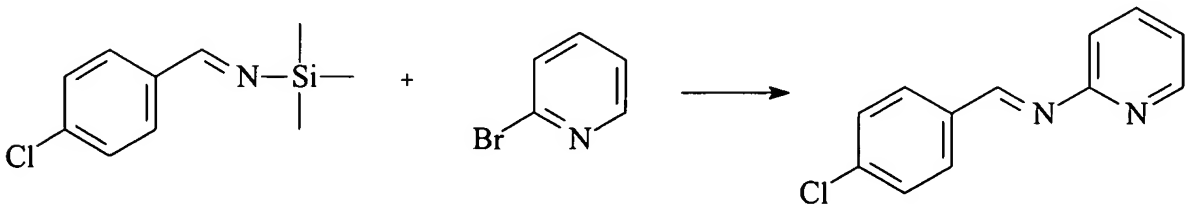
However, Applicants point out that the present invention only exemplifies the Schiff-base type imino group in Example 3, without arguing that only the Schiff-base type of imino group can provide good yields. To the contrary, good yields are achieved in Examples 7 and 8 of the present invention by using the intermediate of Example 1, which is not a Schiff-base type and cannot be predicted from Khomutov at all.

Applicants additionally point out that Khomutov discloses that a primary amine can be converted selectively to an imine in the presence of a secondary amine, however, this disclosure does not in fact result in the selective aromatic nucleophilic substitution of a secondary amine as in the present invention. That is, from the disclosure of Khomutov, one of ordinary skill in the art could not reasonably expect that the aromatic nucleophilic substitution would occur selectively with a secondary amine even in the presence of an imine. This is proven below:

From a review of Jochims et al., *J. Chem. Soc., Perkin Trans. I*, 1998, 3759-3766, it can be seen that a nucleophilic substitution occurs with an imine, as shown in the following reaction scheme:



Additionally, it is reported in Valdes et al., *Agnew. Chem. Int. Ed.*, 2004, 43 (3), 343-345, that imine reacts with 2-bromopyridine which is similar to the substrate of the present invention, as shown in the following reaction scheme:



It is therefore apparent that the selective aromatic nucleophilic substitution of a secondary amine, not imine, in the present invention cannot be reasonably expected from either Hong '670 or

Khomutov. This is even in view of the fact that it is known that a primary amine can be converted selectively to an imine in the present of a secondary amine.

In view of the above, Applicants submit that it is apparent that the Examiner has failed to present a valid prima facie case of obviousness. First, the present invention and Hong '670 cannot be directly compared with one another in terms of the requirement for a recrystallization step. Second, the good yields as achieved in Examples 7 and 8 of the present application (by using the intermediate of Example 1, which is not a Schiff-base type) cannot be expected from Khomutov. Third, the selective aromatic nucleophilic substitution of the secondary amine in the present invention cannot be reasonably expected from any of the cited art.

Thus, the prior art fails to suggest or disclose the present method for preparing Gemafloxacin acid salts, which is characterized in that there is no step for recrystallizing Gemafloxacin, deprotection and preparation of the Gemifloxacin salt are carried out in a single step, and the aromatic nucleophilic substitution of the secondary amine occurs selectively. Therefore, Applicants respectfully submit that the presently claimed invention cannot be expected from the combined disclosures of Hong '670 and Khomutov. Moreover, the present invention achieves unexpectedly superior results in terms of the yield of the target product and the simplicity of the process. The Examiner is therefore requested to withdraw this rejection.

Obviousness-Type Double Patenting

The Examiner has rejected claims 1-11 under the judicially created doctrine of obviousness-double patenting as being obvious over claims 1 and 2 of Hong '670 in view of Khomutov. Applicants respectfully traverse this rejection. As explained above, Applicants have

distinguished claims 1-11 from the cited art. Accordingly, there exists no obviousness-type double patenting over the combined references of Hong '670 and Khomutov. Thus, this rejection is improper and should be withdrawn.

In view of the above, Applicants respectfully submit that the present claims define subject matter which is allowable. Accordingly, the Examiner is respectfully requested to withdrawal all rejections and allow the currently pending claims.

If the Examiner has any questions or comments, please contact Craig A. McRobbie, Registration No 42,874 at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By _____ #42,874

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